IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MYLAN PHARMACEUTICALS INC., Plaintiff, v. CELGENE CORPORATION, Defendant.	Civil Action No. 2:14 cv-02094-ES-MAH Hon. Esther Salas, U.S.D.J. Hon. Michael A. Hammer, U.S.M.J. **RETURN DATE: JULY 7, 2014** **ORAL ARGUMENT REQUESTED**

REPLY IN SUPPORT OF DEFENDANT CELGENE CORPORATION'S MOTION TO DISMISS

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INTRODUCTION

The opposition briefs of Plaintiff Mylan and the Federal Trade Commission seek to obscure the simple issue posed by Mylan's complaint. Mylan asks this Court to force Celgene to sell its patent-protected drugs, Thalomid® and Revlimid®, on terms that Mylan – *but not Celgene* – deems sufficient to satisfy the legitimate business concerns occasioned by the drugs' dramatic fetal safety risks.

Neither Mylan nor the FTC disputes that these concerns are important and objectively real. Indeed, Mylan's counsel represented to Magistrate Judge Hammer that "[t]hese drugs do have legitimate safety concerns. The FDA recognizes that." (Dkt. No. 22 at 5.) When asked whether Mylan would "hold Celgene harmless" from the products liability exposure accompanying any such sale, counsel responded: "Yes, Your Honor, we do recognize that that is a legitimate concern." (*Id.* at 9.) Counsel had little choice. The Court may take judicial notice of the fetal dangers of thalidomide and the tragic birth defects it produced in the 1950s and 1960s, and that the FDA has imposed a restricted distribution system for both drugs. (Dkt. No. 17-1 ['Mot.'] at 1 & n.1, 7-12.) Nor can Mylan wish away the state law tort decisions that expose Celgene to potential liability for *Mylan's* use of the product. (*Id*. at 17 & n.10.)

These concessions doom Mylan's antitrust claim under existing antitrust law, but that law is what Mylan and the FTC seek to change. To do so, they must rewrite the Supreme Court's decision in *Verizon Communications, Inc. v. Law Offices of Curtis V. Trinko*, 540 U.S. 398 (2004), and simply ignore the Court's decision in *Pacific Bell Telephone Co. v. Linkline Communications, Inc.*, 555 U.S.

438 (2009). The tactical decision in both briefs to ignore *Linkline* is particularly telling. Celgene's opening brief showed that "this case is even more like [*Linkline*]" than *Trinko* because in *Linkline*, as here, the claim was not that the defendant had refused to sell altogether. (Celgene has sold samples for bioequivalence testing to other generics who supplied the information and documentation necessary to satisfy Celgene's concerns. (Mot. at 2, 22, 24.)) Rather, the claim in *Linkline*, as here, was that the defendant was "refusing" to deal on terms the *plaintiff* considered reasonable.

Rather than grapple with the dismissal of the *Linkline* complaint, Mylan waves *Linkline* aside in a footnote, claiming that it did not "examin[e] … the scope of a monopolist's duty to deal." (Dkt. No. 24 ['Opp.'] at 17 n.4.) That would be surprising to the *Linkline* Court, which stated that there was "no meaningful distinction between the 'insufficient assistance' claims we rejected in *Trinko* and the plaintiffs' price-squeeze claims in the instant case." 555 U.S. at 450. Indeed, *Linkline* expressly framed its holding in terms of a monopolist's "duty to deal": "*Trinko* thus makes clear that if a firm has no antitrust *duty to deal* with its competitors at wholesale, it certainly has no *duty to deal* under terms and conditions that the rivals find commercially advantageous." *Id.* (emphases added).

The FTC's aversion to *Linkline* is even more total – the FTC does not even mention the case. That may be because, when *Linkline* was pending before the Supreme Court, the FTC argued that "[t]he holding of the Ninth Circuit is unquestionably correct." FTC, *Statement of the Federal Trade Commission* at 3 (May 23, 2008) (Exh. A). Now, the FTC seeks to undo *Linkline*'s unanimous

rejection of the FTC view of the scope of § 2 by mischaracterizing the law. In failing to address the most recent, and relevant, Supreme Court teaching on § 2 duties to deal, the FTC's "amicus" brief disserves the Court.

To adopt the new duty to assist rivals that the FTC and Mylan seek to impose on Celgene, the Court must also embrace two overarching fallacies. The first is to confuse regulation with competition. The advantages generics receive from drug substitution laws, or from Hatch-Waxman, do not create new *antitrust* obligations. They are simply regulatory constraints, like price controls. Mylan's "fundamental fallacy . . . is that the duties [such regulations impose] are coterminous with the duty of a monopolist to refrain from exclusionary practices. They are not." *Goldwasser v. Ameritech Corp.*, 222 F.3d 390, 399 (7th Cir. 2000).

The second fallacy confuses "intent" with actionable exclusionary conduct. Mylan repeatedly argues that, if Celgene acted with the subjective intent of excluding Mylan, antitrust liability will follow. (*E.g.*, Opp. at 19.) That is not the law: "Even an act of pure malice by one business competitor against another does not, without more, state a claim under the federal antitrust laws." *Brooke Group Ltd v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 225 (1993). Because all vigorous competitors seek to defeat their rivals, "'intent to harm' without more offers too vague a standard" for § 2 liability. *Barry Wright Corp. v. ITT Grinnell Corp.*, 724 F.2d 227, 232 (1st Cir. 1983) (Breyer, J.); *see, e.g.*, *A.A. Poultry Farms, Inc. v. Rose Acre Farms*, 881 F.2d 1396, 1402 (7th Cir. 1989) (Easterbrook, J.).

As Celgene shows below, the first step in analyzing a refusal to deal under § 2 is to determine, as an objective matter, whether any legitimate reason exists for

refusing to deal with a rival. *United States v. Microsoft Corp.*, 253 F.3d 34, 59 (D.C. Cir. 2001) ("[O]ur focus is upon the effect of that conduct, not upon the intent behind it. Evidence of the intent behind the conduct of a monopolist is relevant only to the extent it helps us understand the likely effect of the monopolist's conduct."). If such reasons do exist, the refusal cannot be economically "irrational," and hence cannot be exclusionary conduct under § 2. *E.g.*, *Stearns Airport Equip. Co. v. FMC Corp.*, 170 F.3d 518, 523 (5th Cir. 1999). Where, as here, the legitimate grounds for refusing to deal are not only subject to judicial notice but also conceded by Mylan, the inquiry is over.

Although both opposition briefs concentrate heavily on the monopolization claim based on Celgene's alleged unilateral refusal to deal, Celgene has raised other grounds for dismissal, including several dispositive of the entire complaint. To plead a § 2 duty to deal, Mylan needed to allege not only a prior course of dealing and irrational profit sacrifice (Part I.A), but also a means of overcoming a patent holders' right to refuse to sell its invention (Part I.C). To state a § 1 claim, Mylan needed to allege that Celgene and its distributors are economically independent actors (Part. II.B), whose agreement had an effect beyond the FDA-mandated REMS (Part II.A). To make any Thalomid® claim, Mylan needed to allege conduct within the statute of limitations (Part III). Finally, to raise *any* antitrust claim at all, Mylan needed to allege facts regarding potential substitutes for each drug to establish a well-pleaded relevant market (Part IV), as well as Mylan's legal ability to compete in the face of Celgene's patent rights (Part V).

Mylan alleges none of these things. Dismissal should follow.

ARGUMENT

I. SECTION TWO DOES NOT IMPOSE AN AFFIRMATIVE DUTY UPON CELGENE TO ASSIST ITS POTENTIAL COMPETITORS

The Sherman Act allows only "rare instances in which a dominant firm may incur antitrust liability for purely unilateral conduct." *Linkline*, 555 U.S. at 448. The alleged monopolist must, at minimum, employ a "predatory or exclusionary means" of preserving its monopoly. *Steamfitters Local Union No. 420 Welf. Fund v. Philip Morris, Inc.*, 171 F.3d 912, 925 n.7 (3d Cir. 1999) (quotation marks and citation omitted). Exclusionary conduct is defined as "conduct without a legitimate business purpose that makes sense only because it eliminates competition." *Behrend v. Comcast Corp.*, No. 03-6604, 2012 WL 1231794, at *19 (E.D. Pa. Apr. 12, 2012) (quotation marks and citation omitted). Exclusionary conduct thus "requires . . . behavior that – examined without reference to its effects on competitors – is economically irrational." *Stearns Airport*, 170 F.3d at 523.

As shown above, the legitimate business reasons that Celgene (or any seller in Celgene's position) would have to refuse a sale altogether, much less accede to the terms Mylan prefers, are not only undisputed but conceded by Mylan. The monopolization counts may be dismissed for that reason alone. Aware of the legal difficulty these safety and business reasons create, Mylan has attempted to invent new grounds of liability fundamentally at odds with the law.

The "Scheme" Claim. First, Mylan introduces a so-called "scheme" claim. (Opp. at 14-15.) This scheme combines "both [Celgene's] unilateral refusal to sell to Mylan," *i.e.*, Mylan's § 2 claim, and Celgene's "distribution restrictions," *i.e.*,

Mylan's § 1 claim. (*Id.*) In essence, Mylan's argument is that a legally *in*sufficient refusal to deal claim and a legally *in*sufficient vertical distribution claim can somehow be combined into a legally *sufficient* § 2 claim. But the courts have rejected such arguments that the whole is greater than its parts. "[I]t requires no sophistication in mathematical theory to recognize that zero plus zero . . . still equals zero." *Am. Floral Servs v. Florists' Transworld Delivery Ass'n*., 633 F. Supp. 201, 215 n.23 (N.D. Ill. 1986).[1] Again, the *Linkline* opinion that Mylan and the FTC refuse to address disposed of this argument, rejecting Linkline's attempt "to join a wholesale claim that cannot succeed with a retail claim that cannot succeed . . . . Two wrong claims do not make one that is right." 555 U.S. at 457.

Third Circuit law after *Linkline* is entirely consistent. In *West Penn Allegheny Health System, Inc. v. University of Pittsburgh Medical Center*, the Third Circuit reversed a 12(b)(6) dismissal, finding sufficient allegations of exclusionary conduct. 627 F.3d 85, 110 (3d Cir. 2010). But the court held that, on remand, the plaintiff "may not challenge" conduct for which it had "failed to allege . . . antitrust injury," despite an overall scheme claim. *Id.* at n.16; *see SmithKline Beecham Corp v. Apotex Corp.,* 383 F. Supp. 2d 686, 703 (E.D. Pa. 2004) (plaintiff "will not be able to recover" for parts of scheme that do not cause antitrust injury).

Exclusionary Conduct as a Thought Crime. Mylan next argues that,

[1] *See also, e.g.*, *City of Groton v. Conn. Light & Power Co.*, 662 F.2d 921, 928-29 (2d Cir. 1981) ("[W]e reject the notion that if there is a fraction of validity to each of the basic claims and the sum of the fractions is one or more, the plaintiffs have proved a violation of . . . the Sherman Act."); *Intergraph Corp. v. Intel Corp*., 195 F.3d 1346, 1367 (Fed. Cir. 1999).

despite the existence of objectively valid business reasons for refusing to sell without proper safety and indemnity terms, Celgene may be liable if its concerns were not sincere and its ultimate reason was to disadvantage Mylan. (Opp. at 18.) This argument is fundamentally mistaken. *See, e.g.*, *Brooke Group*, 509 U.S. at 225. As (then) Judge Breyer pointed out, because all competitors seek to defeat their rivals, "'intent to harm' without more offers too vague a standard" to measure exclusionary conduct. *Barry Wright Corp*, 724 F.2d at 232; *see also, e.g.*, *A.A. Poultry Farms*, 881 F.2d at 1402 ("Intent does not help to separate competition from attempted monopolization and invites juries to penalize hard competition.").

Rather, the first step in analyzing a refusal to deal is to determine, as an ***objective*** matter, whether any legitimate reason exists for refusing to deal with a rival. *Microsoft Corp.*, 253 F.3d at 59 (§ 2 liability turns on "the effect of [the alleged] conduct, not upon the intent behind it."); *see also, e.g.*, Gregory J. Werden, *Identifying Exclusionary Conduct Under Section 2: The "No Economic Sense" Test,* 73 Antitrust L.J. 413, 416-17 (2006) ("[W]hat matters are the objective economic considerations for a reasonable person, and not the state of mind of" the defendant.). The cases thus require "***conduct*** without a legitimate business purpose," *Behrend*, 2012 WL 1231794, at *19 (emphasis added), and "***behavior*** that … is economically irrational," *Stearns Airport*, 170 F.3d at 523 (emphasis added), not proof of underlying motivation. If an objective reason for a refusal exists, exclusionary ***conduct*** cannot be shown. "A legitimate purpose renders any accompanying purpose [to disadvantage rivals] irrelevant; regardless of motive, no firm has a general duty to injure itself in order to benefit a rival." IIIA Philip E.

Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 773e, at 255 (3d ed. 2005) (citing *Oahu Gas Serv., Inc. v. Pac. Res. Inc.*, 838 F.2d 360, 368-70 (9th Cir. 1988)).[2]

A. Mylan Fails To Allege Prior Dealings Or Profit Sacrifice, Which Are Both Essential Prerequisites For A Section Two Duty To Deal

Mylan devotes the bulk of its § 2 argument (and the FTC all of its arguments) to the proper interpretation of *Trinko*. Celgene quoted *Trinko* for two propositions. First, "[c]ompelling . . . firms to share [their products] . . . is in some tension with the underlying purpose of . . . antitrust law, since it may lessen the incentive for the monopolist . . . to invest in those economically beneficial facilities." (Mot. at 15 (quoting *Trinko*, 540 U.S. at 407-08).) Second, *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985), which concerned the "unilateral termination of a voluntary (*and thus presumably profitable*) course of dealing," was "at or near the outer boundary of § 2 liability." (*See* Mot. at 16 (quoting *Trinko*, 540 U.S. at 409).)

Based on these clear statements, every Circuit Court to decide a refusal to deal case after 2004 has held that an antitrust plaintiff must allege at least (a) termination of a prior course of dealing and (b) profit sacrifice. (*See id.* (collecting cases)). The cases cited by Mylan (with one exception) are entirely in accord.[3] Nonetheless, Mylan and the FTC urge this Court to bypass *Trinko* and

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[2] The *Oahu Gas* Court held that it was reversible error to give an instruction that the jury should "determine if the challenged conduct is supported by legitimate business reasons or whether it was a deliberate effort to injure a smaller rival." *Id.* at 368 & n.3.

[3] *See, e.g.*, *Covad Commc'ns Co. v. Bell Atl. Corp.*, 398 F.3d 666, 673 (D.C. Cir. 2005) ("An antitrust claim base upon the defendant's refusal to cooperate . . .

ignore *Linkline* in favor of two vastly older opinions, *Aspen Skiing* and *Otter Tail Power Co. v. United States*, 410 U.S. 366 (1973). These arguments fail.

Trinko. Mylan contends *Trinko* cannot apply in the pharmaceutical context, because the FCC is different than the FDA. (Opp. at 18.) But the bulk of *Trinko*'s analysis (in Section III) addressed the antitrust standards that apply across all industries. The Court's holding was that, even if other statutes require a monopolist to help its rivals, the antitrust laws do not. The Court addressed the FCC regulatory scheme in Section IV only to determine whether it made sense to fashion a new "exception from the proposition that there is no duty to aid competitors." 540 U.S. at 411. Thus, courts have had no difficulty applying *Trinko* to dismiss pharmaceutical antitrust complaints. *E.g.*, *In re Adderall XR Antitrust Litig.*, No. 13-1232, 2014 WL 2565832, at *5-6 (2d Cir. June 9, 2014);

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can withstand a motion to dismiss only when . . . the defendant had previously engaged in a course of dealing . . . or . . . would ever have done so absent statutory compulsion." (quotation marks and citation omitted)); *Steward Health Care Sys., LLC v. Blue Cross & Blue Shield of R.I.*, No. 13-405, 2014 WL 630678, at *5 (D.R.I. Feb. 19, 2014) ("This unilateral abandonment of a voluntary course of dealing, [and] forsaking of short-term profits . . . have evolved to form the baseline requirements of a § 2 refusal to deal claim."); *Safeway, Inc. v. Abbott Labs.*, 761 F. Supp. 2d 874, 894 (N.D. Cal. 2011) ("Abbott unilaterally terminated a voluntary course of dealing . . . and did so at some expense.").

The sole exception – an unpublished District of Oregon case (Opp. at 20) – ignored binding circuit precedent. The Ninth Circuit requires both prior dealings and profit sacrifice. *See, e.g.*, *MetroNet Servs. Corp. v. Qwest Corp.*, 383 F.3d 1124, 1134 (9th Cir. 2004) (After *Trinko*, there is no "exception to the general 'no duty to deal' rule" where refusal did "not entail a sacrifice of short-term profits."); *see also LiveUniverse, Inc. v. MySpace, Inc.*, 304 F. App'x 554, 556 (9th Cir. 2008) (rejecting argument that "a refusal-to-deal claim does not require '[a previous] affirmative decision or agreement to cooperate' between competitors").

see also Goldwasser, 222 F.3d at 400 (analogizing the FCC context there to the FDA, noting that both "statutory regimes contain their own penalty structures").[4]

Aspen Skiing* and *Otter Tail. Mylan and the FTC ask the Court to ignore the clear teaching of *Trinko* (and to ignore *Linkline* altogether), in favor of broad readings of *Aspen Skiing* and *Otter Tail*. From these older cases, Mylan and the FTC derive a rule that an antitrust plaintiff pleads a viable § 2 duty to deal claim whenever it alleges that a monopolist refuses to sell what it regularly sells, regardless of a prior course of dealing. No such rule can be found.

First, Mylan and the FTC claim that *Otter Tail* did not involve a prior course of dealing. (Opp. at 20 n.6; FTC Br. at 10, 12.) That is wrong; the *Otter Tail* defendant previously had wheeled power to the towns with whom it later refused to deal. 410 U.S. at 368-70; *see Trinko,* 540 U.S. at 410. Moreover, the defendant's contracts with the federal government, on which it based its later refusal to wheel, were summarily declared by the Court to be per se illegal. 410 U.S. at 378-79.

Second, in *Aspen Skiing*, there was no difference between a skier buying a ticket with cash and a skier trying to buy with a voucher, but the defendant refused to continue its prior practice of selling to the latter. *See* 472 U.S. at 593-94 & n.14. Unlike here, where Celgene's legitimate safety and liability reasons are conceded,

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[4] Mylan has wisely abandoned its allegation that the FDA REMS statute somehow compels Celgene to sell its drugs on the terms Mylan prefers. *Compare* Opp. at 27 ("[Mylan never] allege[d] that the REMS statute *creates* a duty to deal,") *with* Compl. ¶ 164 ("[Celgene's] steadfast refusal to allow access to such samples . . . violat[es] . . . § 505-1(f)(8)."). As noted in Celgene's opening brief, this concession makes this an easier case than *Trinko*, where the FCC statute *did* compel Verizon to assist its rivals, but the antitrust laws did not. (Mot. at 15-16.)

the *Aspen* Court concluded that there were no such reasons at all. *Id.* at 610.

To bring this claim partially within the rule of *Aspen*, Mylan and the FTC argue that sales to generics are no different than Celgene's dealings with researchers. (Opp. at 18; FTC Br. at 14 & n.52 (both citing Compl. ¶¶ 161-63).) But neither brief addresses or refutes the obvious differences between research studies that Celgene can control to any extent it deems appropriate and the generic studies that it cannot. (Mot. 17-18.)[5] Another difference is that a sale to a generic for the express purpose of filing an ANDA has as its obvious consequence the expense and distraction of a patent suit, a consequence that Mylan also concedes is inevitable: "[Mylan] want[s] to move forward to get FDA approval, *to get involved in patent litigation*, to try to bring these products [to market]." (Dkt. No. 22 at 12 (emphasis added).)[6] Nor do the briefs dispute that research can lead to new indications and improvements in Celgene's products (*see* Compl. ¶¶ 67 & 162), benefitting Celgene and cancer patients alike in a way that generic testing – solely meant to prove that Mylan has accurately copied Celgene's drug – does not.

Finally, neither the FTC nor Mylan can escape the simple truth that *Trinko*

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[5] As the attorney-advisor to one FTC Commissioner has noted with specific reference to thalidomide, "it is easy to imagine [Celgene] reasonably opting to forego [selling samples to generics in order to] limit the likelihood that the drug is … misused …." Jan M. Rybnicek, *When Does Sharing Make Sense?: Antitrust & Risk Evaluation and Mitigation Strategies*, Comp. Policy Int'l, Apr. 2014, at 4.

[6] As noted, the Court may take judicial notice that Celgene's compound patent on Revlimid®, which claims the drug's active ingredient, does not expire until 2019. (Mot. at 11.) Because all generics must have the same active ingredient as the NDA drug, 21 U.S.C. § 355(j), any generic Revlimid® would infringe, and thus would be excluded unless the patent were declared invalid.

"very severely limits the scope of [claims based on] unilateral refusals to deal under § 2 of the Sherman Act . . . both under the 'essential facilities' and the refusal to deal doctrines as articulated in *Aspen Skiing*." IIIA Areeda & Hovenkamp, *supra*, ¶ 772d3, at 223. Indeed, if Mylan and the FTC's rule were correct, the Supreme Court would have affirmed, rather than reversed, the Ninth Circuit in *Linkline*.[7] It would be more than ironic were the FTC's broadly self-serving interpretation of *Aspen* to be applied in a manner that limits *Trinko* to its facts, when *Trinko* ***expressly*** did the same to *Aspen*. (Mot. at 16.)

***Lannett* and *Actelion*.** As Celgene predicted (*see* Mot. at 22-23), Mylan and the FTC attempt to bolster their proposed extension of § 2 by citing *Lannett* and *Actelion*. But these district court cases are not persuasive, for the simple reason that neither Court explained its actions.[8] Such non-opinions cannot stand against the binding teachings of *Trinko* and *Linkline*. If Mylan is to avoid dismissal, someone must explain why this complaint can survive while the complaint in

[7] Once again, *Linkline* – the opinion with which neither Mylan nor the FTC will contend – refutes their argument. Despite the fact that AT&T "provide[d] plaintiffs *and other independent ISPs* with whole-sale DSL transport service," 550 U.S. at 443 (emphasis added), the Supreme Court concluded that AT&T "would not have run afoul of the Sherman Act" even "[i]f [it] had simply stopped providing DSL transport service to the plaintiffs." *Id.* at 451. This holding – that any intentional decision by AT&T to forego the profit from a sale of product that it regularly sold to other similarly-situated purchasers would not violate the Sherman Act – demonstrates the error of the rule proposed by Mylan and the FTC.

[8] *See Stich v. Bac Home Loans Servicing, LP*, No. 10-1106, 2011 WL 1135456, at *9 (D. Colo. Mar. 29, 2011) (order "without any analysis" is "neither persuasive nor controlling"); *Plocica v. NYLCare of Tex., Inc.*, 43 F. Supp. 2d 658, 664 n.4 (N.D. Tex. 1999) (order with "no legal reasoning . . . is not persuasive").

Linkline did not.[9] Neither Mylan nor the FTC has tried.

In sum, Mylan cannot plead exclusionary conduct, and its § 2 claims fail.

B. The Essential Facilities Doctrine Cannot Salvage Mylan's Claims

The discredited essential facilities doctrine cannot resurrect Mylan's § 2 claims. Mylan never addresses the simple question Celgene posed in its prior brief (Mot. at 19): If that doctrine made no difference as a § 2 theory in *Trinko*, how can it do so here? *See* Areeda & Hovenkamp, *supra*, ¶ 772d3, at 226 ("One is hard-pressed to see any separate vitality remaining in the essential facility doctrine.")[10]

Even if the doctrine did apply, Celgene demonstrated that its drugs are not essential because there are alternate routes to the market, such as an NDA. (Mot. at 20.) Mylan does not contest that it could file an NDA, just as Celgene did. (Opp. at 25-26.) Instead, Mylan claims that it should not have to work that hard, that requiring an NDA would "undermine" the advantages Hatch-Waxman gives to generic drugs. (*Id.*) The premise of this argument is debatable, given Congress's considered decision not to require drugmakers to provide samples of REMS-

[9] To the extent that the *Actelion* Court gave its initial views in court after oral argument, it appears to have misapplied Rule 12(b)(6). The Court refused to decide whether the plaintiffs had alleged a duty to deal, stating that "[t]hat's a decision I need not make and do not reach here. The question, sole question, is whether or not discovery should proceed . . . .". Tr. at 117, *Actelion Pharms. Ltd. v. Apotex, Inc.*, No. 12-cv-5743-NLH (D.N.J. Oct. 17, 2013). But, under *Twombly*, the sufficiency of Mylan's allegations *must* be resolved, and resolved before the massive discovery in an antitrust case "represents an *in terrorem* increment of the settlement value." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558 (2007).

[10] The FTC brief simply blinks on the issue, taking no position on whether the doctrine exists or applies. (FTC Br. at 9, n.23.)

protected drugs. (Mot. at 22.) Nonetheless, even if Mylan were correct about the "policy" of Hatch-Waxman, the argument once again conflates regulation with competition. The antitrust laws care about whether *competition* is undermined, not whether the advantages Hatch-Waxman gives *to certain competitors* – like the advantages FCC law gave to Verizon's rivals in *Trinko* – are undermined. *E.g.*, *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977) (the antitrust laws exist "to protect competition, not competitors").

C. Mylan Ignores Celgene's Patent Right To Withhold Sales

Mylan devotes only a single paragraph and footnote to the impact of Celgene's patent rights on Mylan's § 2 claims. (Opp. at 18 n.5, 24-25.) Neither that paragraph nor that footnote even cite, much less distinguish, Celgene's authorities demonstrating that a forced sale of Thalomid® or Revlimid® would contravene Celgene's patent "right to exclude," or not sell, its inventions. (Mot. at 16 & n. 9 (citing, inter alia, 35 U.S.C. § 154; *Bement v. Nat'l Harrow Co.*, 186 U.S. 70, 88 (1902); *In re ISO Antitrust Litig.*, 203 F.3d 1322, 1328 (Fed. Cir. 2000)).)[11]

Instead, Mylan relies exclusively on the *Bolar* Amendment, which provides that bioequivalency testing is not infringing. 35 U.S.C. § 271(e)(1). The argument is a *non-sequitur*. Celgene never argued that Mylan's use of samples would be infringing. The *Bolar* Amendment does not address, much less abridge, Celgene's antecedent patent right to refuse to sell its invention to anyone for any reason. 35 U.S.C. § 154; *see* 35 U.S.C. § 271(d)(4) (refusal to license).

[11] (*See also id.* at 19 & n.12 (citing several additional cases).)

This antecedent, and fundamental, patent right is a separate reason why Celgene's subjective intent is irrelevant. The courts "will not inquire into [the patent holder's] subjective motivation for exerting his statutory rights, even though his refusal to sell or license his patented invention may have an anticompetitive effect." *In re ISO*, 203 F.3d at 1327; *see also SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1210 (2d Cir. 1981) (Patentee had an absolute right "unilaterally to refuse to license" even if "in an economic sense, it might have been unreasonable").

II. THE FDA REGULATORY SCHEME DOOMS MYLAN'S ATTEMPT TO REPACKAGE ITS SECTION 2 CLAIMS UNDER SECTION 1

Aware of the difficulties of pleading a viable § 2 duty to deal after *Trinko*, Mylan tries to place the same wine into a new bottle by pleading that Celgene's distribution arrangements violate § 1. This repackaging effort is doubly flawed.

A. Neither Mylan Nor The FTC Have A Plausible Response to Celgene's Section One Causation Argument

Celgene's REMS programs – which the FDA both required *and approved* – preclude Mylan from alleging § 1 causation. Specifically, under those programs, the certified pharmacies that distribute Thalomid® and Revlimid® are required to "[d]ispense [the drugs] only after a . . . REMS confirmation number is obtained." (Mot., Exh. D at 3; *see id.*, Exh. G at 3.) Even in the absence of an agreement with Celgene, this provision alone would prevent Celgene's distributors from selling samples to Mylan, because Mylan admits that its bioequivalency studies are outside Celgene's FDA-approved REMS programs. (*See, e.g.*, Opp. at 10.) Thus, Celgene established that, "[i]n the absence of any allegations that the distribution agreements imposed greater restrictions than the regulatory scheme, Mylan's

Section 1 allegations fail to plead causation." (Mot. at 27 (citing, *inter alia*, *City of Pittsburgh v. W. Penn. Power Co.*, 147 F.3d 256, 267-68 (3d Cir. 1998)).)

In response, Mylan first claims that Celgene "misstates the regulatory regime" because the FDA "does not provide step-by-step directions for" REMS. (Opp. at 28.) To the contrary, it is Mylan that ignores the governing statute. The FDA not only can require "the *existence of* REMS," (Opp. at 28), *but also must approve* the drugmaker's step-by-step implementation programs. *See* 21 U.S.C. § 355-1(h). Thus, the FDA specifically approved the provisions of Celgene's REMS programs cited above. Under the *Noerr-Pennington* doctrine, the FDA's approval prevents any antitrust claim, such as Mylan's here, alleging that the governmental action was obtained based on anticompetitive "manipulation of the . . . regulatory regime." (Opp. at 28); *see, e.g.*, *Midland Export, Ltd. v. Elkem Holding, Inc.*, 947 F. Supp. 163, 167-68 (E.D. Pa. 1996) (dismissing antitrust claim because independent government action prevented causation).

Next, Mylan and the FTC both rely heavily on the fact that "the FDA has specifically approved sales of Thalomid and Revlimid to Mylan for the purpose of bioequivalence studies." (Opp. at 28-29, FTC Br. at 19.) But sales by whom? Mylan correctly alleges that the FDA has approved sales *by Celgene*, not sales *by Celgene's distributors*. The FTC's brief acknowledges that the current FDA REMS requirements preclude sales by the distributors when it asserts that "Mylan *may be able to show* that the FDA *would* also allow" distributors to sell to Mylan. (FTC Br. at 19 (emphases added).) Unless and until the FDA does so, however, Mylan cannot plead causation based on its failure to buy from distributors.

In sum, the FDA has granted Celgene, not its distributors, permission to sell to Mylan. *Celgene's* alleged refusal to do so must be measured under § 2, not § 1.

B. Mylan's Own Authority Establishes That Mylan Must Plead That Celgene's Distributors Acted Independently

Mylan concedes the premise of Celgene's concerted action argument, which is that Mylan did not "plead that Celgene's distributors are 'competitors in the alleged market' [or] that they had 'independent reason to harm competition.'" (Opp. at 29.) Mylan's sole argument is that "[n]o case establishes such a pleading requirement." (*Id.*)[12] Simply put, Mylan is wrong.

The very case Mylan relies upon confirms that "a section 1 . . . plaintiff must establish the existence of an agreement." *West Penn*, 627 F.3d at 99. Crucially, that opinion further defines an agreement as "a *common* design . . ., a meeting of the *minds*, or a conscious commitment to a *common* scheme." *Id.* (emphases added). Thus, an antitrust plaintiff must allege that two independent actors agreed to a common plan. *West Penn* therefore belies Mylan's sole effort to distinguish *Siegel Transfer* and *Friedman* as summary judgment cases.[13]

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[12] Mylan and the FTC also cite a host of cases for the unexceptional proposition that vertical restrictions can be subject to § 1 scrutiny. (Opp. at 28 n.13; FTC Br. at 17 n.63.) But neither contends that § 1's concerted action element need not be satisfied in each such case, and neither provides a basis for ignoring the holdings of those Third Circuit cases finding that concerted action was lacking in circumstances such as these. (Mot. at 26 (citing *Harold Friedman, Inc. v. Kroger Co.*, 581 F.2d 1068 (3d Cir. 1978), and *Siegel Transfer, Inc. v. Carrier Express, Inc.*, 54 F.3d 1125 (3d Cir. 1995)).)

[13] Mylan provides no reason why the procedural posture matters. *See Sharp v. Johnson*, 669 F.3d 144, 157 n.18 (3d Cir. 2012) ("Defendants' assertion that *Banks* is inapposite because it was presented . . .in a different procedural posture

Mylan makes no argument and points to no allegation that would allow its § 1 claims to escape the holdings of the Third Circuit's binding decisions in *Siegel Transfer* and *Friedman.* Those claims should be dismissed.

III. MYLAN'S THALOMID® CLAIMS ARE TIME-BARRED

Mylan has expressly alleged that as of "June 24, 2009" – nearly five years before this complaint – it "recognized that further engagement with Celgene would be fruitless." (Compl. ¶¶ 122, 128.) Mylan's claims based on Thalomid are therefore time-barred. (Mot. 27-30 (citing 15 U.S.C. § 15b; N.J.S.A. § 56:9-14).)

Mylan responds on three levels. ***First,*** Mylan contends that it did allege conduct within the limitations period. (Opp. at 30.) Mylan points to its allegation that it "had contacted known wholesale distributors throughout the years[] in an effort to obtain Thalomid and Revlimid." (Compl. ¶ 7.) Such a vague allegation, not even specific to Thalomid®, cannot satisfy *Twombly*'s pleading standard, especially in light of Mylan's more specific allegations that it stopped contacting

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(*i.e.*, a motion for summary judgment) than the instant matter is not persuasive. *Banks* stated that [the rule of] *Turner*, not [Rule] 56," was fatal to defendant's argument). Here, the rule of law applied by *Siegel Transfer* and *Friedman,* not their procedural posture, forecloses Mylan's § 1 claims. Numerous other cases have granted Rule 12(b)(6) motions to dismiss § 1 claims for failure to allege an agreement. *See, e.g.*, *Jack Russell Terrier Network of N. Calif. v. Am. Kennel Club, Inc.*, 407 F.3d 1027, 1035 (9th Cir. 2005) (affirming Rule 12(b)(6) dismissal of § 1 claim because plaintiffs "have not alleged sufficient facts to support a claim that the JRTCA and its affiliates are separate entities pursuing different economic goals, capable of conspiring for Sherman Act purposes"); *Sambreel Holdings, LLC v. Facebook, Inc.*, 906 F. Supp. 2d 1070, 1076 (S.D. Cal. 2012) (dismissing § 1 complaint for lack of "sufficient facts to support the allegation that there was a concerted effort . . . as opposed to unilateral action on the part of Facebook.").

distributors for Thalomid® by 2005, and that it spent "almost five years," *starting in 2004*, attempting to obtain Thalomid®. (Compl. ¶¶ 75-76, 128.)

But even if this general allegation were well-pleaded, it could not restart the limitations period. Mylan knew it was "unable" "to obtain Thalomid samples through normal wholesale distribution channels . . . as a result of [Celgene's REMS]" in 2005. (Compl. ¶¶ 75-76.) Making futile requests "throughout the years" cannot restart the limitations period. *See, e.g.*, *Kaw Valley Electric Coop. Co. v. Kan. Electric Power Coop., Inc.*, 872 F.2d 931, 934 (10th Cir. 1989) ("[N]o new cause of action is created when the victim makes subsequent futile efforts to deal with the violator and is rebuffed.").[14]

***Second*,** Mylan's argument that its "claims . . . would not have accrued, and the limitations period would not have started to run, until Mylan had concrete, measurable damages," fares no better. (Opp. at 30.) The very case Mylan cites, *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 401 U.S. 321 (1971), reveals Mylan's error. There, the Court held that the limitations period "begins to run when a defendant . . . injures a plaintiff's business." *Id.* at 338. Indeed, the Court has "been at pains to explain that discovery of the injury, not discovery of the other

[14] Mylan also posits that "limitations issues are not ordinarily appropriate for resolution on a motion to dismiss." (Opp. at 30, 31 n.5.) This is flatly wrong. Even Mylan's own cases hold that a "statute of limitations defense may be raised in a motion to dismiss." *United States v. Jones*, 916 F. Supp. 383, 386 (D.N.J. 1995) (quotation marks and citation omitted); *see also Kaufhold v. Caiafa*, 872 F. Supp. 2d 374, 380 (D.N.J. 2012) (similar rule for laches). Because the statute of limitations has run, moreover, laches is presumed. Thus, it is *Mylan's* burden to demonstrate that its delay was excusable and not prejudicial. *Santana Prods. v. Bobrick Washroom Equip., Inc.*, 401 F.3d 123, 140 (3d Cir. 2005).

elements of a claim, is what starts the clock." *Rotella v. Wood*, 528 U.S. 549, 555 (2000). Mylan's alleged injury occurred in 2009, when it "recognized that further engagement . . . would be fruitless." (Compl. ¶¶ 122, 128.)[15]

Finally, Mylan invokes the continuing violation doctrine. (Opp. at 31.) But Celgene already explained why this doctrine does not apply, (Mot. at 29-30), and Mylan makes no attempt to rebut Celgene's explanation or authority. Put simply, "[t]he focus of the continuing violations doctrine is on affirmative acts of the defendants," and Mylan has not alleged any affirmative acts within the limitations period. *Weis-Buy Servs. v. Paglia*, 411 F.3d 415, 423 (3d Cir. 2005) (quoting *Cowell v. Palmer Twp.*, 263 F.3d 286, 291-93 (3d Cir. 2001)).

IV. MYLAN DOES NOT PLEAD PLAUSIBLE RELEVANT MARKETS

Mylan's product markets are implausible because Mylan failed to allege any facts concerning potential substitutes for Thalomid® and Revlimid®, including each other. (Mot. at 31-36.) In response, Mylan concedes that antitrust markets "depend[] on the facts." (Opp. at 33.) Nonetheless, Mylan denies any obligation

[15] Mylan's concession that no injury occurred until it could have entered the market is independently fatal to all of its claims, due to lack of causation (*See* Part V, *infra*.) As to Revlimid®, in particular, Mylan concedes that the FDA did not approve its protocols until mid-2013. (Compl. ¶ 142.) Even if Mylan had "formulate[d] a product, conduct[ed] bioequivalence studies, prepare[d] and submit[ted] regulatory filings," (Opp. at 30-31), by the end of 2013, a patent suit by Celgene would have imposed a 30-month stay on Mylan's FDA approval, 21 U.S.C. § 355(j)(5)(B)(iii), until sometime in 2016. According to Mylan's argument here, that means its cause of action regarding Revlimid® has not even accrued. Mylan cannot have it both ways: either it had a claim as to Thalomid® when it alleges Celgene refused to deal in 2009, and that claim is barred, or it has no claim at all as to Revlimid® now.

to plead facts supporting a relevant product market. (*Id.* at 32.) Alternatively, Mylan claims that it has pled a relevant market because the potential substitutes listed by Celgene lack cross-elasticity of demand with Thalomid® or Revlimid®, or are otherwise distinguishable. (*Id.* at 34-37.) Both of these arguments fail.

By urging a "*per se* prohibition against dismissal of antitrust claims for failure to plead a relevant market," Mylan invites this Court to make the same error rejected in *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 436 (3d Cir. 1997).[16] "Where the plaintiff fails to define its proposed relevant market with reference to the rule of reasonable interchangeability and cross-elasticity of demand …, the relevant market is legally insufficient and a motion to dismiss may be granted." *Id.* In other words, that the issue of market definition depends on facts does not relieve Mylan of the obligation to *plead* those facts. Mylan's argument would "absolve [it] of the responsibility under *Twombly* to plead facts 'plausibly suggesting' the relevant submarket's composition." *See, e.g.*, *Jacobs v. Tempur-Pedic Int'l, Inc.*, 626 F.3d 1327, 1338 (11th Cir. 2010).

Queen City's required "reference to . . . reasonable interchangability" dooms Mylan's bid to prove market power solely by its conclusory assertion that Celgene charges "monopoly" prices. (Opp. at 32.) The courts are clear that allegations of supra-competitive prices alone cannot plead a relevant market, including in pharmaceutical antitrust cases. *In re Neurontin Antitrust Litig.*, No. 02-1390, 2013

[16] Mylan's error is understandable, given that its opposition brief never even cites *Queen Pizza*, the seminal case on market definition that has been relied upon by over 300 cases, including published opinions from eight other circuits.

WL 4042460, at *3 (D.N.J. Aug. 8, 2013) ("*Broadcom* did not remove the requirement of establishing the relevant market under the direct evidence method, . . . a plaintiff must still define or refer to the relevant market ...."). Even Mylan's own cases show that "supracompetitive pricing, on its own, is not direct evidence of monopoly power. . . . [S]upracompetitive pricing must be accompanied by restricted output." *Safeway, Inc.*, 761 F. Supp. 2d at 887 (internal citation omitted). Mylan has not alleged restricted output, so cannot satisfy the direct evidence test. Otherwise, an antitrust plaintiff could plead a § 2 claim through circular logic – you have market power because you charge supracompetitive prices, and your prices are supracompetitive because you have market power.

Under *Queen City*, Mylan's complaint needed to allege the boundaries of a relevant product market, including facts about potential substitutes. But Mylan candidly admitted that it did not know "if any" substitutes for Thalomid® or Revlimid® existed. (Compl. ¶¶ 37, 47.) Only after Celgene brought forward judicially-noticeable evidence of potentially competing products did Mylan attempt to distinguish those substitutes in its opposition brief. But Mylan's belated efforts (which would be legally insufficient in any event) fail for the simple reason that none of the facts upon which it relies are alleged in the complaint. It is axiomatic that a motion to dismiss assesses the sufficiency of the pleadings, and that allegations in opposition briefs are not to be considered. *Pa. ex rel. Zimmerman v. Pepsi-Cola Bottling Co.*, 836 F.2d 173, 181 (3d Cir. 1988).

Nor do Mylan's allegations that Thalomid® and Revlimid® "did not exhibit significant, positive cross-elasticity of demand with respect to price with any other

product" salvage its relevant market allegations. (Compl. ¶¶ 39, 49.) Rather, Mylan's verbatim formulation of these allegations underscores the lack of any supporting facts. For example, "cross-elasticity of demand" is simply a label for a standard antitrust test that "measures the responsiveness of the demand for one product [*e.g.*, substitutes] to changes in the price of a different product [*e.g.*, Thalomid® or Revlimid®]." *Queen City Pizza*, 124 F.3d at 438 n.6 (quotation omitted). Mylan makes no allegations that Thalomid® or Revlimid®'s prices changed over time, much less any allegations regarding the effect of any such hypothetical price change on the demand for other products (indeed, Mylan's complaint mentions no other products). Thus, Mylan's complaint "merely restates a commonly used test for market definition without providing any factual basis." *Apple Inc. v. Psystar Corp.*, 586 F. Supp. 2d 1190, 1198 (N.D. Cal. 2008). Such boiler-plate allegations are insufficient to survive a motion to dismiss. *See, e.g.*, *Bayer Schering Pharma AG v. Sandoz, Inc.*, 813 F. Supp. 2d 569, 578 (S.D.N.Y. 2011) (dismissing a complaint alleging "no cross-elasticity of demand between [the monopolized drugs] and . . . potential substitutes," *see* 2010 WL 2208928, at ¶ 48, for failure "to plead sufficient facts to demonstrate that no [drug] is an acceptable substitute"); *Am. Sales Co. v. AstraZeneca AB*, No. 10-6062, 2011 WL 1465786, at *3 (S.D.N.Y. Apr. 14, 2011) (dismissing a complaint alleging that no other substitute was "interchangeable" as a "legal conclusion unsupported by allegations describing . . . the competitive landscape of [alternative] products").

V. CELGENE'S PATENTS PRECLUDE ANTITRUST INJURY

Celgene demonstrated that Mylan had not alleged antitrust injury because it

did not – and could not – allege that it would be able to overcome Celgene's numerous presumptively valid patents for Thalomid® and Revlimid®. (Mot. at 37-39.) In response, Mylan does not refute Celgene's authorities but instead relies on the *Bolar* Amendment, 35 U.S.C. § 271(e)(1), and *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), to contend that such allegations are not necessary here. (Opp. at 38-39; *see also* FTC Br. at 19-20.) Neither authority supports Mylan's argument.

The *Bolar* Amendment is just as irrelevant to assessing antitrust injury as it was to the issue of exclusionary conduct, *see supra* § I.C. Even though Mylan's bioequivalency testing (the subject of the *Bolar* Amendment) would not be infringing, its launch of a generic product – without which Mylan has no antitrust injury – plainly would be infringing. Thus, even Mylan's brief concedes that such a competing product "might infringe a Celgene patent." (Opp. at 39 (emphasis removed).) This concession is undoubtedly accurate; the filing of an ANDA itself is an act of patent infringement, 35 U.S.C. § 271(e)(2)(A), and Mylan's counsel has also represented to Magistrate Judge Hammer that Mylan "want[s] . . . to get involved in patent litigation." (Dkt. No. 22 at 12.).

Actavis likewise has no bearing on the appropriate role of a patent in analyzing antitrust injury. As an initial matter, the plaintiff in that case – the FTC – had no obligation to plead antitrust injury. 15 U.S.C. § 45. Thus, the Supreme Court did not discuss antitrust injury, and the FTC's own brief conceded that circumstances would be different in a private antitrust action for damages, such as Mylan's. *See* Pet'r Br. at 55 n.11, *Actavis*, 133 S. Ct. 2223 (2013) (No. 12-416).

More fundamentally, *Actavis* concerned an antitrust claim premised on a

patent-holder's payment of money to an alleged infringer to settle the patent litigation. Only in this unique circumstance did the five-justice majority conclude that it is "*normally* not necessary to litigate patent validity" in such a case because a "reverse payment itself would *normally* suggest that the patentee has serious doubts about the patent[]." 133 S. Ct. at 2236 (emphases added). In other words, *Actavis* concluded that the patent merits *were* relevant to the antitrust question, but might not need to be analyzed *in that case* if the settlement payment could "provide a workable surrogate for a patent's weakness." *Id.* at 2236-37. *Actavis*'s facts are plainly not present here. There is no viable "surrogate" for the patent merits here, which is why Mylan's complaint ignores Celgene's patents altogether.

In short, neither of Mylan's authorities disturb the fundamental principle that an antitrust plaintiff alleging exclusion has the burden to plead that its competition would have been lawful. *See In re Canadian Import Antitrust Litig.*, 470 F.3d 785, 790-92 (8th Cir. 2006); *Rubber Tire Wheel Co. v. Milwaukee Rubber Works Co.*, 154 F. 358, 364 (7th Cir. 1907)) ("[T]he public [i]s not entitled to profit by competition among infringers."). Mylan cannot do so, and it has not tried.

VI. MYLAN'S STATE CLAIMS DEPEND ON ITS FEDERAL CLAIMS

Mylan concedes that the only wrongful conduct it has alleged to support its state-law claims is "violations of the Sherman Act." (Opp. at 40.) Thus, Mylan's state-law claims fail for the same reasons that its Sherman Act claims fail.

CONCLUSION

For these reasons, Mylan's complaint should be dismissed in its entirety.

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